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(54) Title: METHOD AND DIAGNOSTIC TESTS BASED ON FLOW CYTOMETRIC ANALYSIS OF ANTIGEN-SPECIFIC T LYMPHOCYTES

(57) Abstract: The present invention provides a method for the immuno-diagnosis of diseases with different aetiology (infectious diseases, tumors etc) by measurement of the T cell response (T, B and NK lymphocytes) induced by a set of disease-specific antigens. The method is based on the quantitative determination of antigen-specific T lymphocytes (referred as Ag-Sp), stimulated by using a newly devised pathology-specific antigen or epitope compositions which represent further embodiments of the invention. After stimulation, the selective measurement of the Ag-Sp T lymphocytes is performed by: A) monoclonal antibodies recognizing membrane structures of T lymphocytes and of their sub-populations; B) monoclonal antibodies binding to cytokines accumulating at intracellular level after the stimulation with the antigen; or C) mixtures of A) and B). The flow cytometric detection of the presence of markers of differentiation on T lymphocytes and of intracytoplasmic cytokines allows the acquisition of both qualitative and quantitative results. The invention also provides diagnostic kits for performing the method of the invention.